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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/664,715

09/18/2003

Dimitrios Manoussakis

P-5808

4404

26253

7590

06/27/2007

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EXAMINER

WRIGHT, PATRICIA KATHRYN

ART UNIT

PAPER NUMBER

1743

MAIL DATE

DELIVERY MODE

06/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/664,715

Applicant(s)

MANOUSSAKIS ET AL.

Examiner

P. Kathryn Wright

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-32 and 61-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/2005;9/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group I, species ii (corresponding to claims 14-32 and 61-66) in the reply filed on June 4, 2007 is acknowledged.
2. Claims 1-13, 33-60 and 67-86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions and species, there being no allowable generic or linking claim.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Priority***

3. Acknowledgment is made of applicant's claim for domestic priority under 35 U.S.C. § 119(e).

***Information Disclosure Statement***

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a

separate paper.", see par. [0033] of the instant specification. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 14-32 and 61-66 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The composition of a stationary gel is critical or essential to the practice of the invention, but it is not included in the claim(s), thus is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The specification describes a variety of separator gels that are advantageously used in invention, see par. [0033]. The Examiner believes the composition and/or properties of the gel are essential since only certain fluids (non-Newtonian; thixotropic) are physically stable enough to remain extending upward from a portion of the first region of a stationary gel. These particular gels should not move or change shape except when subjected to substantial centrifugal force (see cols. 1 and 2 of US Patent no. 4,350,593 to Kessler). Thus, the composition of the gel having the necessary rheological properties that enables it to remain extending upward from a

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portion of the first region of a "stationary" gel is believed critical or essential to the practice of the invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 14-28, 30-32, 61, and 63-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 and 61 broadly recite a gel having a second region extending upward from a portion of the first region of the gel. It is not clear from the claims how the gel provides the necessary rheological properties such a second region extends upward from a portion of the first region without being in the process of being centrifuged.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 14-32, and 61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Kessler (US Patent No. 4,350,593).

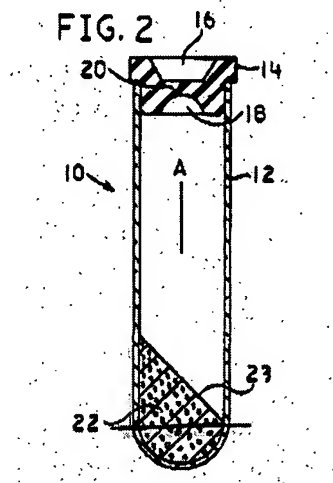
Kessler teaches a container (tube 12) having an upper end, a lower end, and a sidewall between the upper and lower ends having inner and outer walls (see col. 3, lines 53- Figs. 2-4). The tube includes a pierceable closure 14 therein.

Kessler teaches a thixotropic gel 22 located inside the container contacting a portion of the inner wall (col. 1, line 56- col. 2, line 2; col. 3, line 54- col. 4, line 6; see also Figs. 2-5). The thixotropic gel of Kessler is specifically cited in the instant specification as capable of being advantageously used in the invention, see par. [0033] of the instant specification. Thus, the Examiner asserts that since the claimed and prior art gels are identical or substantially identical in structure or composition a *prima facie* case of anticipation is established. See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Furthermore, since the claimed gel composition is the same as the prior art gel it must necessarily exhibit the same rheological properties under the same conditions, i.e. distance between the first and second regions being between 8 to 21 mm; the second region exhibits less than 180 degree circumferential contact with the inner wall, etc.

The figure 2 of Kessler has been modified by the Examiner to include a line or "imaginary upper boundary" that is substantially perpendicular to the longitudinal axis A (see below). The added line is similar to the imaginary upper boundary 44 illustrated in Applicant's Fig. 3. The line has been added to better illustrate what the Examiner considers the second and first regions of the gel (i.e., areas above and below the

horizontal line, respectively). Notice the first region (area below the line) exhibits 360 degree circumferential contact with the inner wall.

Furthermore, it can be seen in the Figures that the first region of the Kessler gel is located at or adjacent to the lower end of the tube and the second region extends upward from a portion of the first region. The stationary gel of Kessler forms a surface 23 located on a plane which is not perpendicular to the long axis A of the tube (see col. 3, line 61- col. 4, line 6.) Preferably, the surface 23 forms an angle of from about 5 degrees to about 60 degrees with the plane normal the longitudinal axis A of the tube, (see col. 3, line 64-65). This clearly falls within Applicant's disclosure of the best-fit plain exhibiting a 45 to 90 degree angle with a plane substantially perpendicular to the longitudinal axis of the container.



### **Conclusion**

11. No claims allowed.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 15, 2007

pkw

A handwritten signature in black ink, appearing to read "P. Kathryn Wright", with a large, stylized loop at the end of the last name.